

## REMARKS

### **Status of the Claims**

Claims 2-4 and 11-26 are currently pending in the application. Claims 2-11, 25 and 26 stand rejected. Claims 12-24 are withdrawn as being drawn to a non-elected invention. Claims 25 and 26 have been amended as set forth herein. Claims 5-10 have been canceled herein. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendments to claim 25 are supported by canceled claims 8-10. The amendment to claim 26 is to clarify the antecedent basis of said second primer, as suggested by the Examiner. Reconsideration is respectfully requested.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claim 26 stands rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (See, Office Action, at page 3). The Examiner states that claim 26 is unclear for reciting "said second nucleotide is cytosine" and recommends amending this phrase to instead recite, "said second primer is cytosine." Applicants have amended claim 26 without prejudice or disclaimer as the Examiner suggests.

Reconsideration and withdrawal of the indefiniteness rejection of claim 26 are respectfully requested.

**Rejections Under 35 U.S.C. § 102(b)**

Ye et al.

Claims 2, 5-7, 11 and 25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ye et al., *Nuc. Acids Res.*, 29(17):E88-8, 1-8, 2001 (hereinafter, "Ye et al."). (See, Office Action, at page 3). Claims 5-7 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that Ye et al. disclose an ARMS-PCR type of approach for detecting SNPs. This type of approach is discussed in the specification at pages 3-4.

Although Applicants do not agree that claim 25 is anticipated by Ye et al., to expedite prosecution, claim 25 has been amended herein without prejudice or disclaimer to recite the limitations of non-anticipated claims 8-10. Therefore, claim 25 is believed to not be anticipated by Ye et al. because Ye et al. do not disclose all of the limitations of claim 25, as amended. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (See, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

Dependent claims 2 and 11 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 25.

Reconsideration and withdrawal of the anticipation rejection of claims 2, 11 and 25 are respectfully requested.

Ferrie et al.

Claims 2-7, 11 and 25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ferrie et al., *Am. J. Hum. Gen.*, 51(2):251-262, 1992 (hereinafter, "Ferrie et al."). Claims 5-7 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claims 5-7. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that Ferrie et al. disclose an ARMS type method for detecting SNPs. Although Applicants do not agree that claim 25 is anticipated by Ferrie et al., to expedite prosecution, claim 25 has been amended herein without prejudice or disclaimer to recite the limitations of non-anticipated claims 8-10. Therefore, claim 25 is believed to not be anticipated by Ferrie et al. because Ferrie et al. do not disclose all of the limitations of claim 25, as amended. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*See, Verdegaal Bros.*, 814 F.2d at 631).

Dependent claims 2 and 11 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 25.

Reconsideration and withdrawal of the anticipation rejection of claims 2, 11 and 25 are respectfully requested.

**Rejections Under 35 U.S.C. § 103(a)**

Ye et al. & Durward et al.

Claims 8 and 9 stand rejected under 35 U.S.C. § 103(a) as being obvious over Ye et al. in view of Durward et al., *BioTech.*, 25(4):608-614, 1998 (hereinafter, "Durward et al."). (*See*,

Office Action, at page 7). Claims 8 and 9 have been canceled herein without prejudice or disclaimer, thus obviating the rejection of claims 8 and 9.

Ye et al. & Durward et al. & Fujisaki et al.

Claim 10 stands rejected under 35 U.S.C. § 103(a) as being obvious over Ye et al. in view of Durward et al., further in view of Fujisaki et al., U.S. Patent No. 5,935,520 (hereinafter, "Fujisaki et al."). (See, Office Action, at page 8). Claims 10 has been canceled herein without prejudice or disclaimer, thus obviating the rejection of claim 10.

However, claim 25 now recites the textual subject of cancelled claim 10. Amended claim 25, however is not obvious in light of the cited references, especially Ye et al., for the following reasons.

In the present invention according to amended claim 25, the analysis is carried out by measuring pyrophosphoric acid in dry analytical element without performing electrophoresis. The analysis by measuring pyrophosphoric acid has the following advantages as compared with the analysis by electrophoresis:

(1) In PCR, pyrophosphoric acid is generated in a stoichiometric amount as a by-product. Thus, one molecule of pyrophosphoric acid is generated every time one nucleotide is incorporated. Therefore, the analysis by measuring pyrophosphoric acid based on chemical reaction is much more highly quantitative as compared to the electrophoresis system where fluorescence is measured by intercalator.

(2) A quantitative assay of pyrophosphoric acid using a dry analytical element can be completed in about 5 minutes, while electrophoresis requires 30 minutes or more. Therefore, an

assay of pyrophosphoric acid using dry analytical element is rapid as compared with electrophoresis.

(3) The procedure (operation) of an assay of pyrophosphoric acid using a dry analytical element is convenient where one drop of the reaction solution is blotted onto the slide (dry analytical element).

(4) Some intercalators (such as ethidium bromide) used in electrophoresis are carcinogenic, while such harmful reagents are not used in the assay of pyrophosphoric acid.

Thus, because Ye et al. do not disclose or suggest all of the limitations of the presently claimed invention, as recited in amended claim 25, the presently claimed invention cannot be obvious in light of the disclosure of Ye et al. Furthermore, the disclosures of the secondary references of Durward et al. and Fujisaki et al. do not cure the defects of the lack of disclosure of Ye et al.

Ye et al.

Claim 26 stands rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Ye et al. (*See*, Office Action, at page 10). Applicants traverse the rejection as hereinafter set forth.

The Examiner states that Ye et al. do not disclose or suggest primers that have two different mismatched nucleotides which are adenine in the first primer and cytosine in the second primer. However, the Examiner notes that Ye et al. discusses "strong," "weak" and "medium" mismatches and the possibility of using combinations thereof. Thus, the Examiner states that

this disclosure is sufficient to make this particular choice of mismatch base identities obvious to one of ordinary skill in the art.

As stated above, the analysis of the present invention is carried out by measuring pyrophosphoric acid in dry analytical element without performing electrophoresis. The analysis by measuring pyrophosphoric acid has the advantages as compared with the analysis by electrophoresis as discussed above, with respect to the rejection of claim 10.

Thus, because Ye et al. do not disclose or suggest all of the limitations of the presently claimed invention, as recited in amended claim 25, the presently claimed invention cannot be obvious in light of the disclosure of Ye et al. Claim 26 depends directly from claim 25 and thereby incorporates all of the unique elements and features of claim 25. Thus, claim 26 is also not obvious in light of the disclosure of Ye et al. for the same reasons that claim 25 is not obvious.

Reconsideration and withdrawal of the obviousness rejection of claim 26 are respectfully requested.

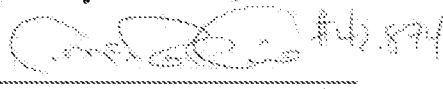
CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: July 27, 2007

Respectfully submitted,

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